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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,229	01/29/2002	Peter Herold	2001-1907A	3386
513	7590	07/28/2004	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			REYES, HECTOR M	
		ART UNIT		PAPER NUMBER
				1625

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/048,229	HEROLD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Hector M Reyes	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 June 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2 and 8 is/are rejected.
- 7) Claim(s) 3-7, 9 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION****Election acknowledgement**

Applicant's election with traverse of Group I in the reply filed on June 25 2004 is acknowledged. The traversal is on the grounds that Applicants takes the position that since the PCT Authority has acknowledged unity of invention, the PTO should not require restriction because according to PCT article 27 (1):

No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

This is not found persuasive because:

- The said PCT article does not particularly indicate that the lack of unity determination in the International stage of a PCT needs to remains intact once the national Application is file.
- Moreover, the language of the said PCT article 27 also provides for the application of national Law in the processes following the filing of the national stage application, see for instance other sections of the said article.
- Applicants has not provide any evidence that there is indeed an special technical feature liking the groups outlined by the Examiner and
- The inventions listed as Groups I through IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
  - Group I, is ***drawn to a process for the preparation of compounds of formula I***, which does not necessarily required any of the claimed compounds in claimed in Groups II, III or IV for its preparation. Compounds of Formula I can be prepared by other alternative processes.

- Compounds claimed in Groups II, III and IV can be used in multiple other synthesis.
- Compounds claimed in Groups II, III and IV contain significantly different chemical structures and belong to different classes and subclasses.

Indeed a given references anticipating or suggesting any of the compounds claimed in Groups II, III or IV cannot be used to reject any of the claims of Group I under 35 USC 102 or 35 USC 103.

The requirement is still deemed proper and is therefore made FINAL.

### **Specification Objections**

The specification is objected base on lack of clarity:

On page 8, substituents on the structure (II a) are missing, on page 10, substituents on structure (II) are missing and on page 11, substituents on structure (II a) are missing.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the said claims, the phrase "if necessary" is used in the description of the claimed process. However, it is unclear when the conditions followed the said phrase would be required and when the said conditions would be unnecessary. Therefore, the required process steps and conditions remain indefinite and ambiguous. For instance, in claim 1, page 27, last paragraph it is said" in the presence of water and if necessary, an

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acid to form a compound of formula III" It is unclear when the said acid would be required and when it would be enough to carry the said step in the presence of water. Clarification is hereby requested by indicating those conditions that would require the use of an acid.

### **Claims Objections**

Claims 2-7 and 9 are objected because the said claims depend on rejected claims 1, 2 or 8.

### **Allowable Subject Matter**

No prior art disclosing or suggesting the instant invention was found. The closest art relevant to the instant invention was found in Herold et al, Journal Organic Chemistry, 54 (5), pages 1178-1185 (1989). The said reference has been acknowledged by Applicants in page 10 of the instant specification.

Herold, one of the instant inventors, teaches a method for the preparation of hydroxyethylene dipeptide isosteres. However, the said derivatives are not embraced by formula I of the instant claims and they only have three chiral centers, while the instant target contains four, thus it would not be obvious to predict the behavior of the additional substituent in the known synthetic pathway as well as the stereocontrol described in claim 8.

### **CONCLUSION**

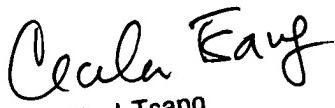
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes, PhD JD whose telephone number is (571) 272-0691. The examiner can normally be reached on M-F (9:00 AM-5:30 PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rita Desai can be reached on (571) 272-0684. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Hector M. Reyes PhD JD  
Reg. # P-54,846  
AU 1625  
July 20, 2004

  
Cecilia J. Tsang  
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